

Remarks

Applicants note that the filing receipt as well as the Office Action Summary page acknowledges that there are 33 claims on file. The Restriction at paragraph 2 of the Office Action, however, is based upon 41 claims. The preliminary amendment is submitted herewith to reconcile this difference and to bring the claimed subject matter into conformance with that of the preceding patent application, U.S. patent application Serial No. 09/922,906, of which the present application is a continuation.

Upon entry of the preliminary amendment, claims 1 to 22 and 29 to 41 will be pending in the above-identified patent application. Claims 23 to 28 have been canceled. Claims 34 to 41 have been added.

In view of the remarks that follow, reconsideration and withdrawal of the election/restriction requirement is requested respectfully.

Discussion of Election/Restriction Requirement Pursuant to 35 U.S.C. § 121

The Office Action requires Applicant to select one of the following allegedly patentably distinct inventions for examination:

- Group I: Claims 23-28, drawn to piperidinyl/tetrahydropiperidinyl compounds, classified in class 546, subclass various, depending on species election.
- Group II: Claims 1-22, 29-41, drawn to remaining compounds wherein Z^3 is other than piperidine/tetrahydropiperidine, classified in class various, subclass various, depending on species election

(Office Action at 1). The Office Action alleges that the "compounds of groups I or II differ in elements, bonding arrangements and chemical properties to such an extent that unpatentability of group I compounds would not necessarily imply unpatentability of group II compounds" and that the

“searches for each group of compounds are not co-extensive of the other and [thus] independent examinations are required” (Id.).

The Office Action notes, however, that the claims of group I, *i.e.*, claims 23-29 drawn to piperidiny/tetrahydropiperidiny compounds, have already issued in U.S. Patent No. 6,277,865. Accordingly, Applicants elect group II for prosecution in the present patent application.

The Office Action further requires Applicants to elect “a single disclosed species” when electing group II (Office Action at 1) (emphasis in the original). Applicants respectfully traverse the species election/restriction requirement.

I. The Species Election/Restriction Requirement Is Improper Based On The MPEP §803.02 And Relevant Case Law

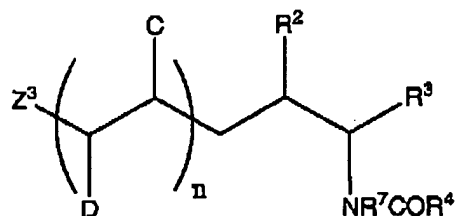
Applicants submit respectfully that the election/restriction is improper for dividing Applicants’ Markush claim in contravention to the requirements of MPEP §803.02 and the case law.

A. MPEP §803.02 Considerations

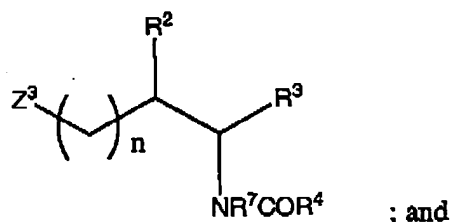
MPEP §803.02 provides that there is no basis for an Election/Restriction of a Markush claimed invention where two factors are met, *i.e.*,

... compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature ...

Applicants’ claimed invention meets the aforesaid factors. That is: (A) the compounds of the claimed invention all share a substantial structural feature, *i.e.*, the compound of the formula



or



; and

B) their compounds share a common utility, *i.e.*, being useful for a method for treating a patient suffering from, or subject to, a disease state associated with a physiologically detrimental excess of Factor Xa activity.

Moreover, it is well-established that the Office Action must provide reasons and/or examples to support conclusions when issuing a restriction requirement. MPEP § 803. The Office Action, however, has completely ignored this requirement. Indeed, the Office Action has provided *no* evidence or technical reasoning to support its apparent conclusion that the remaining compounds included within the Z³ Markush group do *not* share a common utility and do *not* share a substantial structural feature. Accordingly, the species election/restriction requirement is improper on its face for failing to comply with the requirements set forth in the MPEP.

B. Case Law Considerations

As detailed below, well-settled case law such as, for example, *In re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980) and *Ex parte Dahlen and Zwilgmeyer*, 42 U.S.P.Q. 208 (Bd. App., 1938), supports Applicants' position that the present restriction requirement is improper because, as stated above, the

Office Action has provided *no* evidence or technical reasoning to support its apparent conclusion that the remaining compounds included within the Z³ Markush group do *not* share a common utility and do *not* share a substantial structural feature.

In re Harnisch, 206 U.S.P.Q. 300 (CCPA 1980)

In *In re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980), the court found that an invention claimed in a Markush type claim was proper for compounds having a common utility and “*a single structural similarity*” (emphasis added). In particular, in agreeing with its earlier decisions, the court stated that a Markush group was proper where there is a

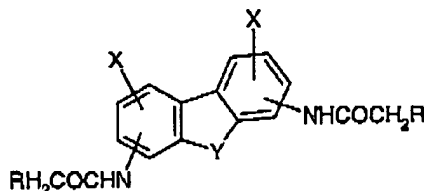
grouping of compounds having the *same nuclei but side chains wherein there was a wide variation* ... and had *a community of properties justifying their grouping* ... was not repugnant to principles of scientific classification.

In re Harnisch, 206 U.S.P.Q. at 305 (emphasis added). The Court held that, when such criteria exist, there is unity of invention within the claimed Markush group. *Id.*

Applicants' claimed invention meets the standard of *In re Harnisch* as it indeed has the requisite single structural similarity (*i.e.*, the substantial structural feature from MPEP §803.02) and shares a common utility, as noted above. Therefore, there is no propriety for the present Election/Restriction.

Ex parte Dahlen and Zwilgmeyer, 42 U.S.P.Q. 208 (Bd. App., 1938)

In addition, in *Ex parte Dahlen and Zwilgmeyer*, a Markush compound of formula



was found to be proper wherein Y was defined as a bivalent bridge radical that was further defined in Markush format consisting of the following 12 members, $-\text{CH}_2-$, $-\text{CO}-$, $-\text{C}=\text{C}-$, $-\text{CH}_2\text{CH}_2-$, $-\text{NH}-$, $-\text{N-alkyl}-$, $-\text{O}-$, $-\text{S}-$, $-\text{N}=\text{N}-$, $-\text{N}=\text{NO}-$, $-\text{SO}_2-$ and $-\text{COCO}-$. Particularly noteworthy regarding that compound, was that the Markush grouping was found to be acceptable even though the variable Y provided for variations in the size and classes of tricyclic ring systems, i.e., the central ring could be defined to have a ring size of 5 or 6 that include a ring selected from a cyclopentadienyl ring, cyclohexadienyl ring, phenyl ring, or one of four different heteroaryl rings (pyrrolyl, furanyl, thienyl or pyridazinyl). Indeed, Applicants' Z^3 Markush group gives rise to exceptionally less variability in the classes of compounds encompassed by its *single structural similarity* than those in *Ex parte Dahlen* (i.e., only X varies between S, SO and SO_2).

Accordingly, reconsideration and withdrawal of the species election/restriction requirement is requested respectfully.

II. Provisional Election

Although Applicant submits respectfully that the imposed species election/restriction is improper, in an attempt to advance the prosecution of this application to allowance, Applicants provisionally elect the species where Z^3 is optionally substituted dihydropyridyl. Applicants submit that once the compounds of the present invention are found to be novel, then the other Groups defined by the Examiner that contain any compositions of matter containing those compounds should also be found to be novel and rejoined. Further, Applicants reserve the right to pursue any compounds that remain after prosecution of the instant patent application in a future divisional patent application.

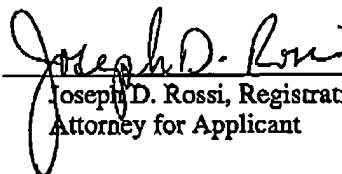
II. Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

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Joseph D. Rossi, Registration No. 47,038
Attorney for Applicant

Aventis Pharmaceuticals Inc.
Patent Department
Route #202-206 / P.O. Box 6800
Bridgewater, New Jersey 08807-0800
Telephone: 908-231-3410
Telefax: 908-231-2626
Docket No. USA2797 US CNT